

REMARKS

STATUS OF THE CLAIMS.

Claims 1-35, 37-39, 41-43, 45-49, 51, and 53-55 are currently pending in the application. Of such claims, 1-34, 38, 45-48, and 53-55 are withdrawn from current consideration. Claims 35, 37, 39, 49, and 51 are amended herein to more clearly describe embodiments of the invention. These changes introduce no new matter and support is present in the application and claims as originally filed. The changes are made without prejudice and are not to be construed as abandonment of any previously claimed subject matter or agreement with any objection or rejection of record. Accordingly, entry of the Amendment is respectfully requested.

REJECTIONS TO THE CLAIMS

35 U.S.C. §112 First Paragraph.

New Matter

Claims 35, 39, 41-43, and 49 were rejected in the current Office Action under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification so as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. The Office Action alleged that the amendments submitted in Applicants' Response of October 25, 2004 contain new matter. The Office Action alleged that the terms "vertebrate," "insect," "fish," "amphibian," and "reptile" within the phrase "wherein the sperm is from a vertebrate, a mammal, a human, a canine, a feline, a rodent, an insect, a fish, an amphibian, or a reptile" were not supported by the specification as originally filed. Applicants respectfully traverse.

As discussed with Examiner Jiang (telephone call of October 25, 2005), paragraphs 18, 40, and 45, very clearly list the above species and classifications. Since the species and classifications are explicitly recited within the specification, it is not new matter to amend the claims to include such explicitly recited species and classifications.

Notwithstanding the clear support for the full amendment of October 20, 2004, Applicants herein amend claims 35, 39, and 49 to focus on particular embodiments at this time. It should be noted that the Listing of Claims which begins on page 2 of this submission, assumes that the amendment of October 20, 2004 was entered in full. The current changes are marked

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accordingly. As explained above and in the telephone call of October 25, 2005, support for the amended claims can be found in the specification, *e.g.*, at paragraphs 18, 40, and 45. Since no new material is added in any way by such amendment, Applicants respectfully request its entry. Also, since the species and classifications are clearly supported by the specification as filed, Applicants request that the rejection be withdrawn.

Enablement/Written Description

Claims 35, 37, 41-42, 49, and 51 were rejected in the current Office Action under 35 U.S.C. §112, first paragraph as allegedly lacking enablement/written description for sulfonated compounds other than LSA (or its various other descriptives) in combination with spermicide other than Nonoxynol 9TM. Applicants amend in part and traverse in part.

Sulfonated Compounds other than LSA

Applicants note that, as discussed with Examiner Jiang on October 25, 2005, the Office Action incorrectly characterizes Applicants' argument. Applicants amended the claims in the Response of October 20, 2004, and further amend the claims herein. The current Office Action confuses Applicants' Response of October 20, 2004 with the Response of January 16, 2004.

In regard to the current Office Action's contention that the specification does not provide written description enablement for "any sulfonated compounds," etc., Applicants herein amend claims 35, 37, 49, and 51. While Applicants believe that the current claims are enabled by the written description of the specification, such claims are amended herein in order to expedite prosecution.

The claims are modified by deleting the terms: "polyvinylsulfonic acid," "a sulfonic acid derivative of a porphyrin," "a sulfonic acid derivative of a triphenylmethane," "a sulfonic acid derivative of a stilbene," "a sulfonated phenylpropane," and "a sulfonated kraft lignin."

Applicants point out that polyanetholesulfonic acid (PASA) in claims 35 and 37 is a clearly defined compound. *See, e.g.*, Aldrich Catalog Handbook of Fine Chemicals 1996-1997, p. 1197, and Mohan, et al. (1992) *Antiviral Research*, 18:139-150, etc. Additionally, numerous examples of sulfonic azo dyes are given in the specification, *e.g.*, Evans Blue, Chicago Sky Blue, Direct Yellow 50 and Congo Red at paragraph 58. Claims 49 and 51 are also amended herein to recite LSA (rather than "sulfated lignin"). Support for the changes to claims 49 and 51 is replete

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throughout the specification and claims as filed. *See, e.g.*, paragraph 22. Since such changes add no new matter, Applicants respectfully request their entry.

Since the amended claims no longer include the language upon which the rejections were based, the rejections under 35 U.S.C. §112 First Paragraph are moot and Applicants respectfully request that they be withdrawn.

Spermicide

In regard to the Office Action's allegation that the use of "spermicide" in claims 37, 43, and 51 is not enabled by the written description of the specification because only Nonoxyol 9™ is described, Applicants respectfully traverse. Based on the wording of the Office Action, Applicants assume that the rejection is a written description rejection and address it accordingly. As explained in the phone call with Examiner Jiang on October 25, 2005, Applicants again note that their previous discussion of spermicides does not seem to have been considered in preparation of the current Office Action and is therefore presented again herein.

The Office Action contended that spermicide is seen to be "purely functional language." The Office Action also alleged that such "functional language" is admonished by the court in University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (CAFC, 1997), hereinafter Lilly. The Office Action quotes from Lilly, and emphasizes that satisfaction of the written description requirement "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." The Office Action alleged that since "spermicide" is a "purely functional distinction" and Nonoxyol 9™ is the only spermicide illustrated within the specification, that the written description for "spermicides" as a group is not satisfied. Applicants respectfully point out that other M.P.E.P. sections and case law are more pertinent than Lilly in the current analysis.

The M.P.E.P. analyzes Lilly in regard to written description requirements at, *inter alia*, §2163(II)(A)(3)(a)(ii). Notwithstanding the Office Action's characterization of Lilly, however, the M.P.E.P. clearly states that situations exist "where one species adequately supports a genus." For examples of such situations, the M.P.E.P. cites to Rasmussen, 650 F.2d at 1214, 211 USPQ at 326-27; In re Herschler, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979); and In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973).

In re Herschler is particularly apt in the current context. The specification in Herschler disclosed corticosteroid in DMSO, while the claims were drawn to methods using a mixture of a “physiologically active steroid” and DMSO. The claims were found to be enabled in terms of written description. The court in Herschler stated that:

use of known chemical compounds in a manner auxiliary to the invention must have a corresponding written description **only so specific as to lead one having ordinary skill in the art to that class of compounds.** Herschler at 718 (emphasis added)

The situation in Herschler is easily analogous to the current application. As steroids were in Herschler, spermicides herein are known chemical compounds, and need only be described well enough to lead one of ordinary skill in the art to the class. The current specification contains sufficient written description for the class in question, by use of the term “spermicides” and the example of Nonoxynol 9TM. *See, e.g.*, paragraph 51.

Applicants submit that the term “spermicide,” similar to the phrase “physiologically active steroid” in Herschler is well recognized by those of skill in the art. Those of skill would be aware of, and familiar with, various different spermicides and would easily understand, and not miscomprehend, the description in the specification. In other words, those of ordinary skill in the art would recognize the class of “spermicides.” *See, e.g.*, definition of “spermicide” in Merriam-Webster Online Dictionary at www.m-w.com. Spermicides are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend. *See also Amgen v. Hoechst*, 314 F.3d 1313 (Fed. Cir. 2003). Because of the above reasons, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. §112 Second Paragraph.

Claims 35, 37, and 41-42 (or claims 35, 37, 49, and 52 – it is unclear from the Office Action since both groups are listed) were rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite by failing to particularly point out and distinctly claim the subject matter regarded by applicants as the invention. More specifically, the Office Action alleged that the phrases “a sulfonic acid derivative of a porphyrin, a sulfonic acid derivative of a triphenylmethane, a sulfonic acid derivative of a stilbene,” and “derivatives thereof” in such claims render them indefinite. The Action states that one of ordinary skill in the art could not ascertain and interpret the

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metes and bounds as to “derivatives thereof” in the current claims. Applicants herein amend the claims to remove such language.

Again, Applicants believe the unamended claims to be clear and not to be indefinite. However, in order to expedite prosecution, Applicants herein amend claims 35, 37, 49, and 51 to remove the above phrases. Applicants respectfully point out that claims 41 and 42 do NOT contain, and have never contained, the cited language and that claim 52 was previously cancelled in a prior Response. Also, none of the cited claims contains the terms “derivative(s) thereof.” Because the amended claims do not contain the language protested by the Office Action, Applicants respectfully request that the rejections be withdrawn.

35 U.S.C. §102(b).

Pillai

Claims 35, 39, 41-42, 49, and 51 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Pillai et al. (1997 *Aquatic Toxicology*, 37:139-156). Applicants respectfully traverse.

The Office Action alleges that Pillai discloses compositions having lignin-derived macromolecules “containing lignosulfonates and/or lignosulfonic acids, isolated from a lignin, and a sea urchin sperm in an aqueous solution (a pharmaceutical excipient) in varying concentrations, wherein LDM may inhibit the sperm acrosome reaction.”

While Applicants believe that Pillai does not disclose all elements of the unamended claims (*e.g.*, because Pillai includes glutaraldehyde or paraformaldehyde which would render the composition to be unacceptable as a pharmaceutical excipient no matter the other constituents comprising the composition), Applicants herein amend claims 35, 39 (and hence its dependents 41-42), and 49, to recite “wherein the sperm is from a mammal, a human, a canine, a feline, or a rodent.” Support for such change is replete throughout the application as filed. *See, e.g.*, paragraphs 18, 40, and 45.

Applicants amended the same claims in the prior Response (October 20, 2004) and amend them again herein to more clearly claim the current embodiments. Applicants again note that the current Office Action mischaracterizes the Response of October 20, 2004 in which Applicants amended the claims in question. The current Office Action confuses Applicants’ January 16, 2004 Response and Applicants’ October 20, 2004 Response.

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In order for a reference to anticipate a claim “the reference must teach every element of the claim.” M.P.E.P. §2131. Applicants respectfully submit that Pillai does not teach every element of the amended claims. For example, Pillai does not teach compositions comprising a sperm from “a mammal, a human, a canine, a feline, or a rodent” as recited in amended claims 35, 39, and 49. Also, Pillai does not comprise a spermicide as recited in claim 51.

Again, Pillai deals with sperm from sea urchins (an echinoidea), thus, Pillai does not include all the limitations of the amended claims and cannot anticipate the current claims. Because Pillai does not recite all of the limitations of the claims as amended, Applicants respectfully request that the rejection be withdrawn.

Vines

Claims 35, 39, 41-42, 49, and 51 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Vines et al. (1996, *Marine Environmental Research*, 42(1-4):138). Applicants respectfully traverse.

As with Pillai above, Vines does not teach every element of the amended claims. For example, Vines does not teach compositions comprising a sperm from “a mammal, a human, a canine, a feline, or a rodent” as recited in amended claims 35, 39, and 49. Vines concerns sperm from sea urchins (an echinoidea) and herring (a fish), thus, Vines does not include all the limitations of the amended claims and cannot anticipate the current claims. Also, Vines does not comprise a spermicide as recited in claim 51. Because Vines does not recite all of the limitations of the claims as amended, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. §103(a).

Pillai/Vines and Anderson

Again, as explained in the phone call with Examiner Jiang on October 25, 2005, the current Office Action completely ignores Applicants’ last Response in terms of the Pillai/Anderson 103(a) rejection. As per the Examiner’s request, Applicants herein repeat their argument. It will be appreciated that the same logic applies to both Pillai and Vines in combination with Anderson.

Claims 37, 43-44, and 51-52 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Pillai et al. (1997 *Aquatic Toxicology*, 37:139-156), or Vines et al. (1996, *Marine Environmental Research*, 42(1-4):138, in view of Anderson et al. (USPN 6,063,773). Applicants

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note that claims 44 and 52 were cancelled in a previous Response. For the remaining rejected claims, Applicants respectfully traverse.

In brief, Applicants submit that the Office Action has not established a *prima facie* case of obviousness because the record fails to provide the elements necessary for a *prima facie* case.

M.P.E.P. §2144.06 quotes from *In re Kerkhoven* in setting forth the guidelines for establishing *prima facie* obviousness based on combining equivalents “known for the same purpose.”

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, in order to have *prima facie* obviousness, the prior art compositions, as well as the resulting third composition, must have been useful for the same purpose. *Kerkhoven* based its rejections upon combination of two conventional spray-dried detergents. *Kerkhoven* at 1072. The court held that both components were detergents which were used for the very same purpose, *i.e.*, they were dry, free-flowing detergents.

To try to establish *prima facie* obviousness, the Office Action alleges that

[o]ne having ordinary skill in the art at the time the invention was made would have been motivated to employ a lignosulfonate or a lignosulfonic acid in combination with a spermicide such as nonoxynol-9 in a pharmaceutical composition since both a lignosulfonate or a lignosulfonic acid, and the known spermicide, nonoxynol-9, are known to be useful in a composition for contraception or inhibiting fertilization based on the cited prior art.
Office Action at page 16.

However, Applicants respectfully emphasize that the Office Action has mischaracterized the purposes of the elements (namely the lignosulfonate or lignosulfonic acid and the spermicide) in the current application. In other words, Applicants submit that the lignosulfonate or lignosulfonic acid and the spermicide are not “compositions known useful for the same purpose [...] form[ing] a third composition to be used for the very same purpose.” The Office Action roughly lumps both LSA and spermicides together as “known to be useful in a composition for contraception or inhibiting fertilization.”

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Applicants respectfully point out, though, that such characterization is an incorrect analysis. Lignosulfonate/lignosulfonic acid (LSA), etc., is not a spermicide; rather, it, *e.g.*, inhibits acrosome reaction of sperm. The specification emphasizes that the LSA herein does not act as a spermicide (*i.e.*, does not kill or immobilize sperm as used herein). *See, e.g.*, paragraphs 42, 50 (which states that the “compounds. . . can allow the sperm to remain mobile while preventing or inhibiting fertilization of the oocyte by the treated sperm”), etc. In marked contrast, a spermicide kills or immobilizes sperm. As mentioned above, Merriam-Webster Online Dictionary defines a spermicide as “a preparation or substance (as nonoxynol-9) used to kill sperm.” Unlike LSA, the spermicide Nonoxynol 9TM is actually cytotoxic to a number of cells in addition to sperm.

Thus, it can be seen that the two components are not useful for the very same purpose, which is required in order to create *prima facie* obviousness by combining equivalents.

The current components are as if in Kerkhoven (by analogy) one component had been a detergent, but the other component had been a bleaching agent or the like. Both may have been present together, but would have had different purposes. Similarly in the present application the LSA and the spermicide can be present together, but they still have quite different purposes.

The Office Action overly generalizes the uses/purposes of the compositions by setting the definition of “purpose” so far out from the actual intended uses/purposes of the compositions that the categorization is meaningless. Roughly defining the use/purpose of the compositions to be “contraception or inhibiting fertilization,” is similar to defining HIV drug cocktails, which include different compositions (*e.g.*, nucleoside analogs such as AZT and ddI and a protease inhibitor) as “obvious” because their use/purpose is to treat HIV patients. The end goal may be to treat the patient, but the actual uses/purposes of the compositions are vastly different. Similar analogies can be made to basically any combination drug treatment therapy.

Applicants submit that the Office Action generalizes the definition of use/purpose of the composition elements so much as to be meaningless. Since the LSA and the spermicide serve different purposes/uses, as noted above, *prima facie* obviousness cannot be established and Applicants respectfully request that the rejection be withdrawn.

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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. In the event that substantive matters are felt to remain, the Examiner is invited to telephone the undersigned at (510) 769-3507.

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